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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,036	04/27/2001	Sang He Lee	20796000120	1505

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EXAMINER

NOLAN, PATRICK J


ART UNIT PAPER NUMBER

1644

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/845,036	Applicant(s) Lee et al.	
Examiner Patrick J. Nolan	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 10, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-75 is/are pending in the application.
- 4a) Of the above, claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 21-31 and 33-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Part III DETAILED ACTION

1. Applicant's election with traverse of Group I, claims, 21-31 and 33-75 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the base claim should be considered a linking claim and the dependent claims as species, further Applicant argues the groups were classified incorrectly and a correct classification would not require an undue search and consideration for all the groups. Lastly, Applicant argues the Examiner has construed the claims to be limited to protein antigens, when they are not. This is not found persuasive because a linking claim is only appropriate when there are proper species within the base claim. The polynucleotide of claim 32 does not serve as an antigen, therefore it does not meet the requirement of functional similarity required to keep all the claims together as one genus and many species within the linking claim. Applicant's invention is drawn to provoking an immune response in a farm animal by administering an antigen in claims 21-31 and 33-75, upon reconsideration the appropriate classification for this invention would be class 424 subclass 184.1. However, the classification, for group II, is correct, class 514 subclass 44 is drawn to body affecting compositions with polynucleotides, as is Applicant's claim. A search of these two disparate classes would constitute an undue burden on the Examiner. Lastly, in regards to Applicant's comment the examination of antigen is being limited to protein antigens, the Examiner is only reading the claims in light of the specification. If, Applicant can point to other chemical compounds described as antigens in the specification to be used in the recited methods the Examiner will duly consider.

The requirement is still deemed proper and is therefore made FINAL.

2. Upon reconsideration of the instantly pending claims the following species election is required.

This application contains claims directed to the following patentably distinct species of the claimed invention.

The following species election is required.

An antigen derived clostridium

- i) toxin B
- ii) toxin A
- iii) a protein from a C. difficile (VPI10463) cell
- iv) clostridium difficile spore

Each antigen has unique physical, chemical and biological properties, which gives each species unique enablement and search

requirements. The species are therefore patentably distinct from one another.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for which prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 21-31, 33-37, 43-75 are generic.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 9:00 to 5:30 pm.

9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
June 16, 2003

